

ARJOHUNTLEIGH

GETINGE GROUP

FLOWTRON ACS800 +TRI PULSE

INSTRUCTIONS FOR USE



CE
0086

...with people in mind

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GENERAL SAFETY

Before you connect the system pump to a mains socket, read carefully all the installation instructions contained within this manual.

The system has been designed to comply with regulatory safety standards including:

- EN60601-1:1990/A13:1996 and IEC 60601-1:1988/A2:1995.
- UL60601-1 and CAN/CSA C22.2 No. 601.1-M90.
- EN60601-1:2006 and IEC 60601-1:2005
- AAMI/ANSI ES60601-1:2006 and CAN/CSA C22.2 No.60601.1(2008)

Safety Warnings

- **It is the responsibility of the care giver to ensure that the user can use this product safely.**
- **Make sure that the mains power cable and tubeset or air hoses are positioned to avoid causing a trip or other hazard, and are clear of moving bed mechanisms or other possible entrapment areas.**
- **Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the pump. The pump's case must only be removed by authorised technical personnel. No modification of this equipment is allowed.**
- **The mains power socket/plug must be accessible at all times. To disconnect the pump completely from the electricity supply, remove the plug from the mains power socket.**
- **Disconnect the pump from the mains power socket before cleaning and inspecting.**
- **Keep the pump away from sources of liquids and do not immerse in water.**
- **Do not use the pump in the presence of uncontained flammable liquids or gasses.**
- **Only the pump and garment/insert combination as indicated by ArjoHuntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and garment combinations are used.**
- **The Flowtron® ACS800 + Tri Pulse system is NOT intended for use in the Home Healthcare Environment (e.g. private dwellings or nursing homes).**

Caution (applicable to the USA market only)

- **US Federal law restricts this device to sale by or on the order of a physician.**

Precautions

For your own safety and the safety of the equipment, always take the following precautions:

- Do not expose the system to open flames, such as cigarettes, etc.
- Do not store the system in direct sunlight.
- Do not use phenol-based solutions to clean the system.
- Make sure the system is clean and dry prior to use or storage.

Electromagnetic Compatibility (EMC)

This product complies with the requirements of applicable EMC Standards. Medical electrical equipment needs special precautions regarding EMC and needs to be installed in accordance with the following instructions:

- The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.
- Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical electrical equipment.

- If this equipment needs to be used adjacent to other electrical equipment, normal operation must be checked before use.
- For detailed EMC information contact ArjoHuntleigh service personnel.

Expected Service Life

The pump has an expected service life of seven years. To maintain the condition of the pump have the pump serviced regularly according to the schedule recommended by your ArjoHuntleigh distributor.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the system. Failure to observe this caution could result in injury, or in extreme cases, death.

Environmental Protection

Incorrect disposal of this equipment and its component parts, particularly batteries or other electrical components, may produce substances that are hazardous to the environment. To minimise these hazards, contact ArjoHuntleigh for information on correct disposal.

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1. Introduction

About this Manual This manual is your introduction to the Flowtron[®] ACS800 + Tri Pulse system, which is a *Flowtron* ACS800 pump enabled for use with both Tri Pulse and uniform DVT garments. Refer to “Accessories” on page 29 for a list of the garments which can be used. You must read and fully understand this manual before using the system.

Use this manual to initially set up the system, and keep it as a reference for day-to-day routines and as a guide to maintenance.

If you have any difficulties in setting-up or using the system, contact your local ArjoHuntleigh sales office, listed at the end of this manual.

Intended Use The intended use of this product is to prevent Deep Vein Thrombosis (DVT). The garments are single patient use only. It is not for use in the home healthcare environment.

The *Flowtron* ACS800 + Tri Pulse system should be used as part of a prescribed plan of care (refer to “Indications” on page 3).

About *Flowtron* ACS800 + Tri Pulse The application of external pneumatic compression has two effects:

- Augments venous blood flow velocity, thereby reducing stasis.
- Enhances fibrinolytic activity to reduce the risk of early clot formation.

The system comprises a pump that can be used in conjunction with an extensive range of ArjoHuntleigh inflatable garments, including foot, calf and calf & thigh versions. The pump automatically adjusts to the correct therapy profile depending upon which garment type (foot, uniform DVT calf or calf & thigh, or Tri Pulse calf or calf & thigh) is connected.

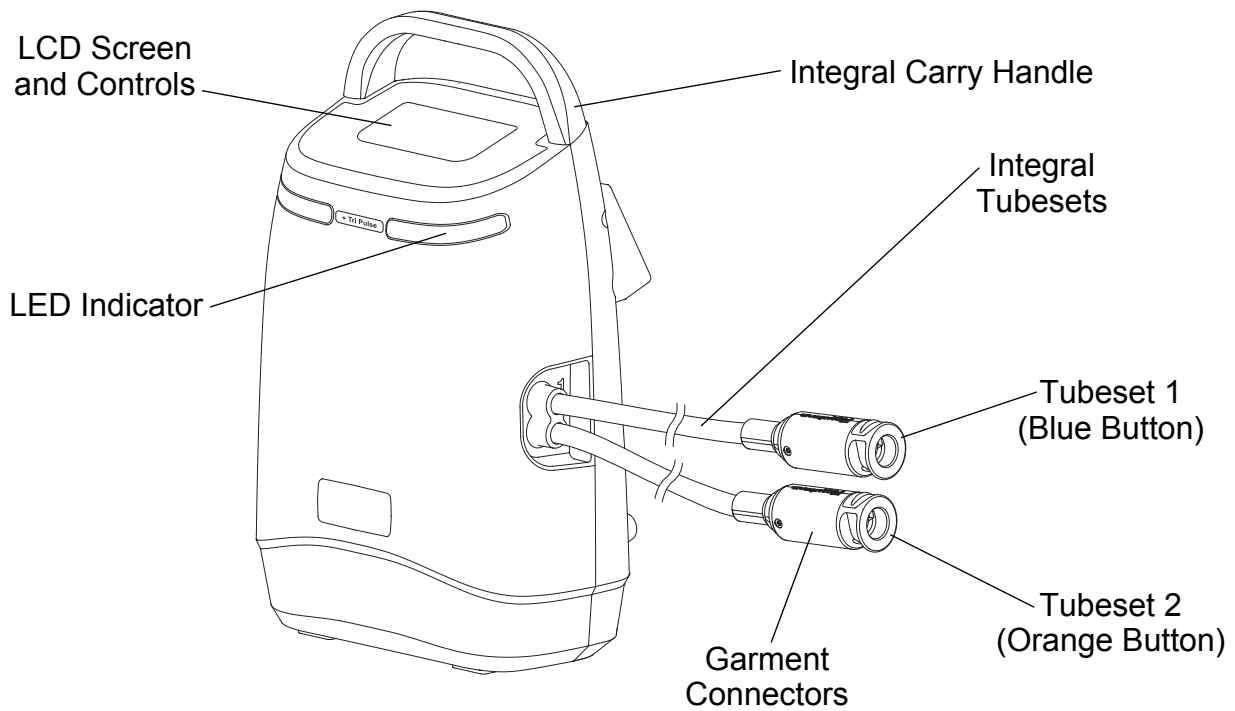
The tubeset is integral to the system and cannot be disconnected from the pump.

The mains power supply is the primary power source for the pump. The pump incorporates an internal battery pack, which is a secondary power source to back up the pump in the event of failure or disconnection (accidentally or deliberately) from the mains power supply.

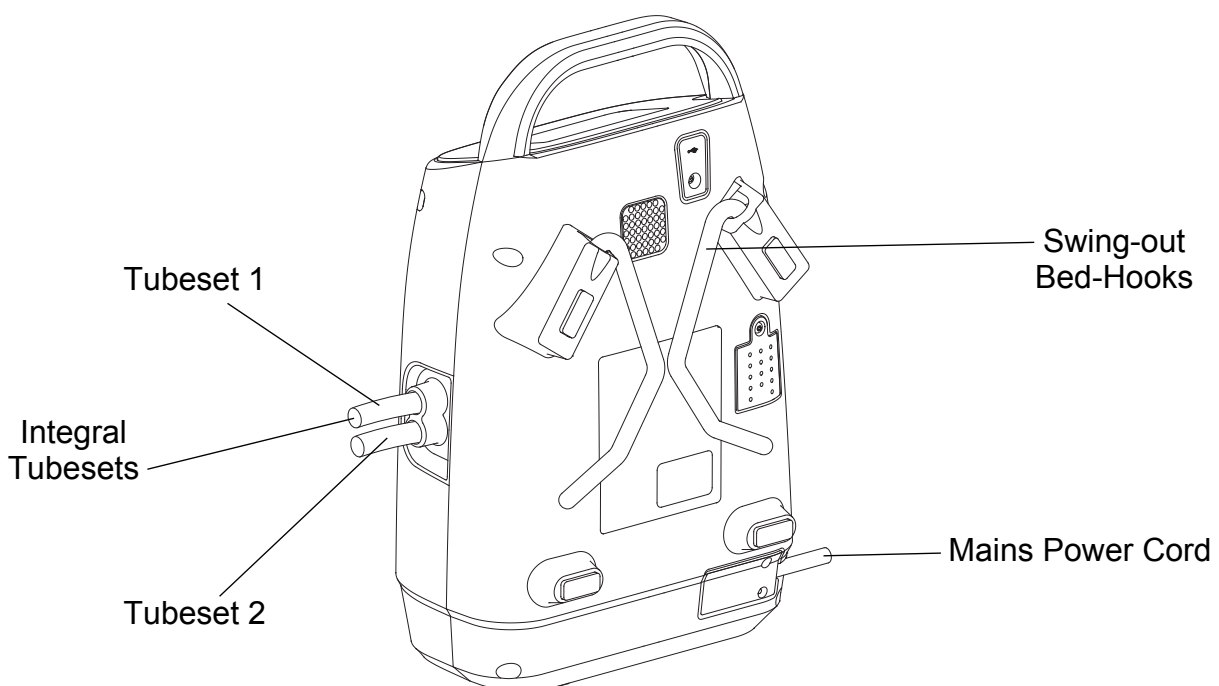
The system is intended for use ONLY in Professional Healthcare Facilities (e.g. hospitals or physicians' offices).

A full technical description of the *Flowtron ACS800 + Tri Pulse* system can be found in the Service Manual, part number SER0020, available from your local ArjoHuntleigh sales office.

Pump: Front View



Pump: Rear View



2. Clinical Applications

Indications The intended use of the *Flowtron* ACS800 + Tri Pulse system is to help prevent Deep Vein Thrombosis (DVT). The system should be combined with an individualised monitoring programme.

These systems represent one aspect of a DVT strategy; if the patient's condition changes the overall therapy regimen should be reviewed by the prescribing clinician. The above are guidelines only and should not replace clinical judgement.

Depending on the garment type used, other clinical applications are also appropriate.

The FG foot garment, in particular, has a wide range of clinical applications.

Full details for clinical applications are included in the packaging of every garment.

The type of garment used on an individual patient must be specified by a physician.

- Contraindications**
- Uniform DVT Calf/Calf & Thigh and Tri Pulse Calf/Calf & Thigh Garments***
- The system, when used with the uniform DVT calf/calf & thigh and Tri Pulse calf/calf & thigh garments, should **not** be used in the following conditions:
1. Severe arteriosclerosis or other ischemic vascular diseases.
 2. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
 3. Known or suspected acute deep vein thrombosis, thrombophlebitis or pulmonary embolism.
 4. Any local condition in which the garments would interfere, including:
 - Gangrene
 - Recent skin graft
 - Dermatitis
 - On untreated, infected leg wounds.
- Foot Garments***
- The system, when used with the foot garments, should **not** be used in the following conditions:
1. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
 2. Known or suspected acute deep vein thrombosis, thrombophlebitis or pulmonary embolism.

3. Any local condition in which the garments would interfere, including:
 - Gangrene
 - Recent skin graft
 - Dermatitis
 - On untreated, infected leg wounds



If you are unsure of any contraindications refer to the patient's physician before using the device.

Cautions

1. Proper garment application and connection to the pump is essential.
2. Garments should be positioned in such a way that there is no potential for sustained pressure points on the skin and underlying tissues. Lower limb positioning in relation to the garment and tubing should also be considered particularly in a patient that is unconscious, cannot feel or has reduced sensation and/or ability to move their leg(s).
3. While using the system, the patient's skin should be inspected frequently and regularly, paying particular attention to bony prominences such as the malleolus and heel. It is recommended that these checks should be performed not less than every hour if the patient cannot feel or has reduced sensation and/or ability to move their leg(s); in all other patients, perform these checks not less than every 6 hours.
4. Clinical judgement is required to determine if the patient's skin condition requires additional protective measures, or if the therapy should be discontinued and an alternative modality used.
5. Garments should be removed immediately if the patient experiences tingling, numbness, or pain, and the physician notified.
6. When used for DVT prevention, continuous external pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the system is encouraged.
7. The system should be **USED WITH CAUTION** on patients with:
 - Insensitive extremities.
 - Diabetes.
 - Impaired circulation.
 - Fragile or impaired skin.

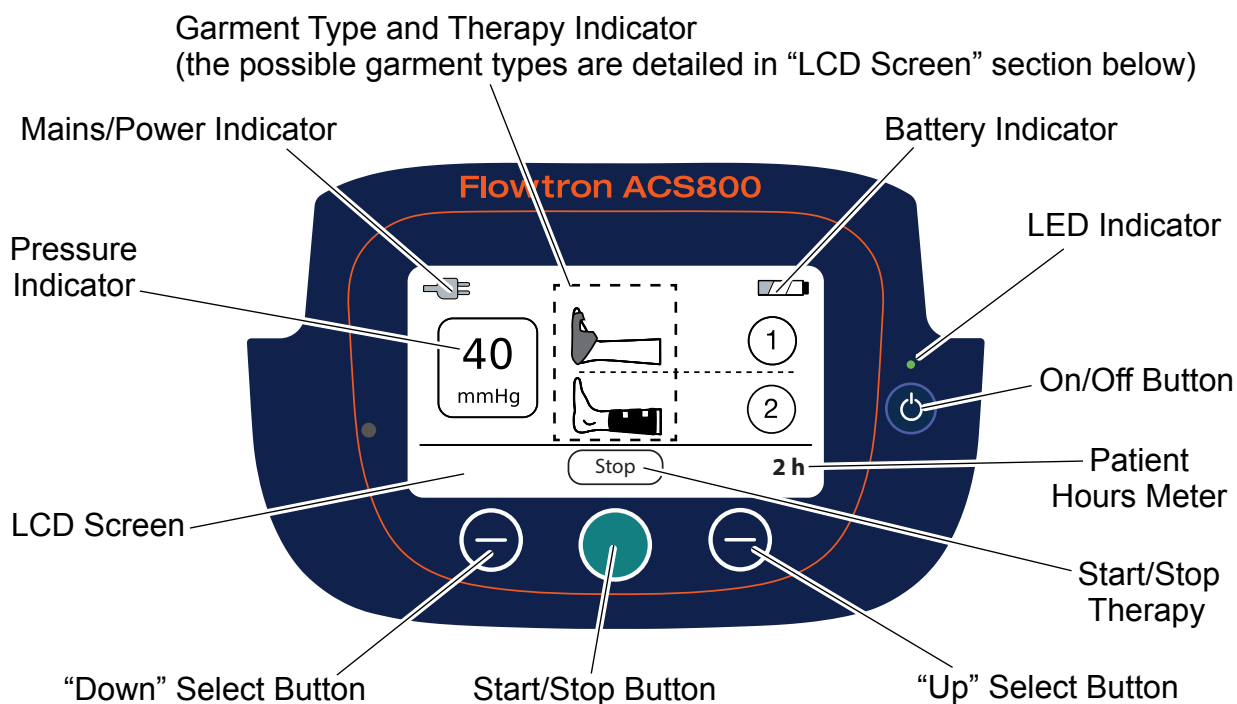
 *These are guidelines only and should not replace clinical judgement and experience.*

Guidelines and Recommendations

- General Recommendations**
- While using the system, the patient's limbs should be checked not less than every six hours, and more often if the patient has known circulatory or skin problems, or is diabetic.
 - Note: Many patients are at risk for pressure ulcers on the heel. Use of the foot garments does not negate the necessity for heel protection and proper skin care.
 - Clinical judgment should be used to determine if the patient's skin condition requires additional measures, or if the treatment should be discontinued and alternative modalities used.
 - ArjoHuntleigh does not recommend the use of compression stockings with its system. If these are ordered by the physician, the clinician should ensure that the compression stockings are properly measured, applied and worn by the patient. Any compression stocking used should be routinely checked to ensure continued proper fit and application, in addition to assessing the condition of the skin.
 - Where appropriate, patients should be instructed in the proper use of the system, the purpose of therapy and that any problems should be reported to the nursing staff.
- DVT Prophylaxis**
- The system should be applied to the patient pre-operatively, prior to the induction of anaesthesia.
 - The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
 - If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.
 - In the non-surgical patient, the system should be initiated immediately the risk of DVT formation is identified.

3. Controls, Alarms and Indicators

Control Panel With Typical LCD Screen View in Run Mode



On/Off Button and LED Indicator

Press the On/Off button to power up the pump from its unpowered state and put it into Standby (refer to “Standby Screens” on page 11).

 *Connecting the pump to the mains power supply will automatically power up the pump from its unpowered state and put it into Standby, without having to press the On/Off button.
Make sure the system has been arranged so that the power cable and garment hoses do not pose a trip or strangulation hazard.*

The adjacent LED indicator shows the pump status:

LED Colour	Mains Power	Pump Status
Extinguished	Disconnected	Off
Amber	Connected	Off
Amber	Connected or disconnected	Standby
Green	Connected or disconnected	Run

To switch off the pump, press and hold the On/Off button for approximately 2 seconds until the LCD screen goes blank, and then release.

If you switch off the pump and then press the On/Off button to power it back up:

- If the mains power is disconnected, the pump runs the diagnostic tests and then goes into Standby.
- If the mains power remains connected, the pump goes into Standby and does not run diagnostic tests.

Start/Stop Button

This has the following functions depending on the text or icon displayed above the button:

- To start or stop therapy.
- To confirm the option selected in the Options menu.

When the pump is in Standby, press the Start/Stop button to put the pump into the Run mode and start therapy; the LED indicator adjacent to the On/Off button will change to green and the LEDs on the front case will be illuminated green.

To stop the therapy and put the pump into Standby, press and hold the Start/Stop button for approximately 2 seconds until the Standby screen is displayed and then release the button. The LED indicator adjacent to the On/Off button changes to amber and the LEDs on the front case are extinguished.

“Up” and “Down” Select Buttons

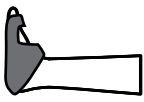
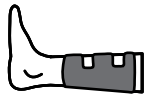
These have the following functions depending on the text or icon displayed above the buttons:

- To select the Options menu.
- To move up and down the Options menu.
- To mute certain audible alarm conditions.

LCD Screen

This displays the pump operating mode and status:

1. Foot, uniform DVT calf (or calf & thigh) or Tri Pulse calf (or calf & thigh) therapy indications. These show what garment type is connected to each tubeset and when each garment is being inflated:

	Foot Garment		Uniform DVT Calf or Calf & Thigh Garment		Tri Pulse Calf or Calf & Thigh Garment
---	-----------------	---	---	---	---

- All therapy indications are initially shown as grey to indicate they are deflated.
- A therapy indication changes to black to show it is inflating.
- The therapy indication reverts to grey when it starts to deflate.
- The garment connector on the end of each tubeset has a push button which is colour-coded

and has a number marked on it: blue “1” or orange “2”. The numbers corresponds with the “1” and “2” on the right side of the LCD screen. Where the tubesets enter the side of the pump, the top tubeset is marked “1”.

2. Pressure indication: this is the inflation pressure applied to the garment, as follows:
 - Foot garment: 130 mmHg.
 - Uniform DVT calf and calf & thigh. The pressure is adjustable between 35 - 65 mmHg. To be adjusted only by authorised personnel. The pump will default to the last pressure set.
 - Tri Pulse calf and calf & thigh garments: 45 mmHg.
3. Mains power indications:

	The pump is connected to the mains power supply.
	The pump is not connected to the mains power supply, but is powered by the internal battery only.

4. Battery indication:
 - When the pump is connected to the mains power supply, then:
 - If the battery is fully charged, the indicator will be static and show “full”.
 - If the battery is not fully charged, the indicator will “scroll” from “empty” to “full” to indicate that the pump is being charged.
 - When the pump is NOT connected to the mains power supply, then the indicator is static and shows the charge remaining in the battery:

	Battery Empty		Battery 1/3 Full
	Battery 2/3 Full		Battery Full

 *The battery has a service life of 5 years (600 charge cycles). It is not user replaceable and must be replaced as part of the service procedure.*

5. Patient Hours Meter: if this is selected, the total therapy time is shown (in hours). Refer to “Changing Options” on page 16 to select and/or clear the Patient Hours Meter.

- This is the pump run time since the Patient Hours Meter was last cleared.
 - The factory default is to NOT show the Patient Hours Meter on the LCD screen.
6. Warning and alarm indications (refer to “Troubleshooting” on page 23).

LED Indicators on the Front Case

There are two sets of LED indicators on the front case of the pump. Their status is as follows:

LED Colours	Pump Status	Warnings/Alarms
Extinguished	Off or Standby	- -
Green (Static)	Run	• No fault detected. • Warning only detected.
Red (Flashing)	Run	Fault detected with full audible and visual alarm

4. Operation

General These instructions cover the day-to-day operation of the system. Other operations, such as maintenance and repair, should only be carried out by suitably qualified personnel.

Refer to “Controls, Alarms and Indicators” on page 6 for a description of the controls, indicators and LCD screen.

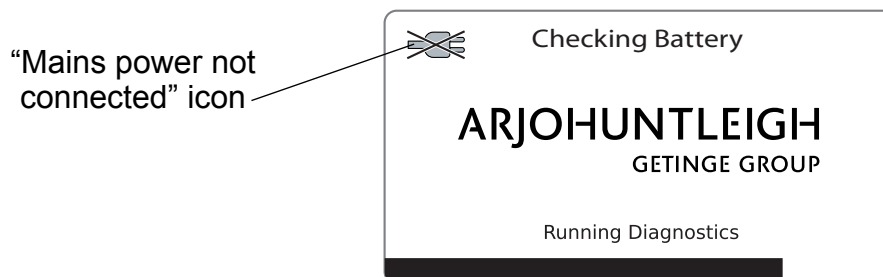
 *If the operation or performance of the pump changes during use, refer to “Troubleshooting” on page 23 of this IFU before calling a service engineer or contacting your local ArjoHuntleigh sales office.*

Start Up To switch on the pump, do one of the following:

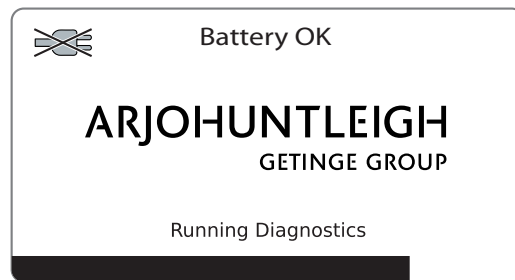
- Connect the pump to the mains power supply using the power cable provided. The pump will power up automatically and start running a diagnostic test, and display the following screen:



- If operating from just the battery (disconnected from the mains power supply), press the On/Off button. The pump will power up and start running the diagnostic test, and display the following screen. Note the “Checking Battery” text and the “Mains power not connected” icon at the top of the screen:

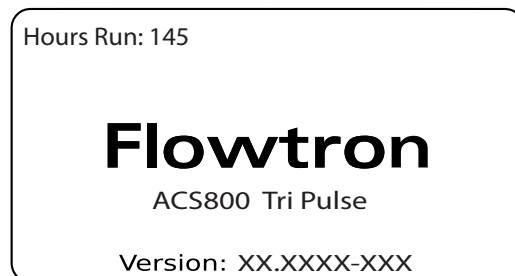


After a few seconds, the following screen is displayed, showing “Battery OK”:



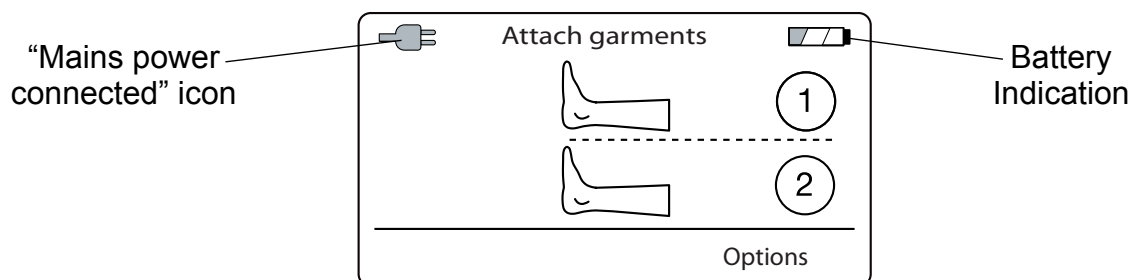
 *If the text at the top of the screen says “Low Battery” then you must connect mains power before you can start therapy.*

- At the end of the diagnostic test, the following screen is displayed, showing the “Hours Run” at the top, the software version of the pump at the bottom and “ACS800 Tri Pulse” below “Flowtron”:



 *The “Hours Run” value displayed on this screen is for service use only, and is different to the “Patient Hours Meter” displayed during therapy. Refer to “Controls, Alarms and Indicators” on page 6 for the “Patient Hours Meter”.*

Standby Screens The “No Garments” Standby screen is then displayed:



There are two “leg” icons with no garments attached and the text “Attach garments” at the top of the screen; this indicates that no garments are currently connected to either tubeset.

 *There is no text above the Start/Stop button until at least one garment is connected to a tubeset.*

Apply the prescribed ArjoHuntleigh garment(s) to the patient by following the instructions included in the garment packaging.

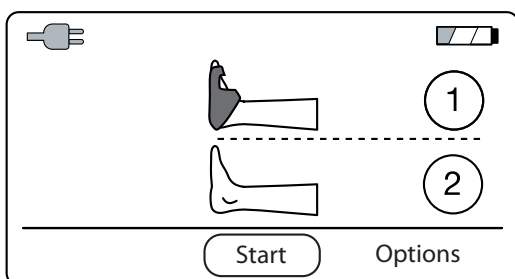
 *Garments are for single patient use only. Do not use the garments on a different patient after treatment.*

Connect the garment(s) to the pump by pushing the garment connector firmly into the pump tubeset connector until it “clicks”.

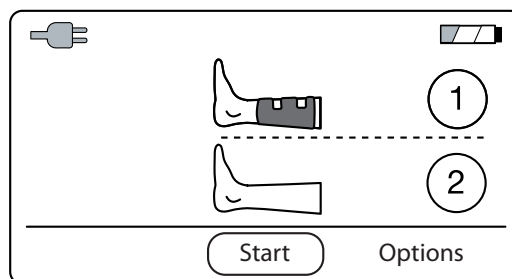
The pump LCD screen will show which garments are connected to each tubeset connector: the garment connector with the blue push button is “1” and the one with the orange push button is “2”.

If any pump options (Audio Alarm Volume, Patient Hours Meter or Language) need to be changed, they must be changed before the patient therapy is started. Refer to “Changing Options” on page 16.

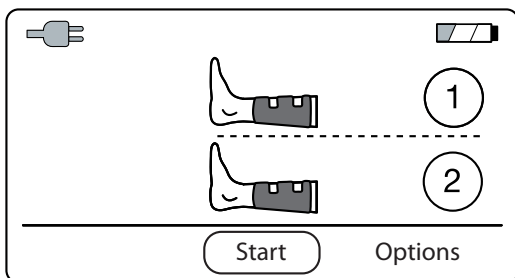
The following six screens show typical Standby screens with different garment configurations:



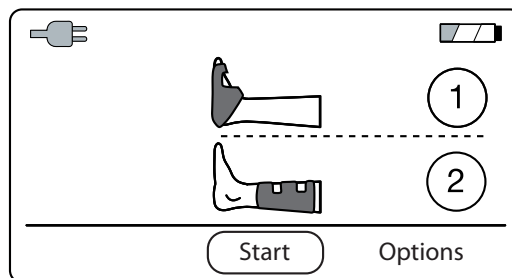
Foot Garment
Connected to Tubeset 1



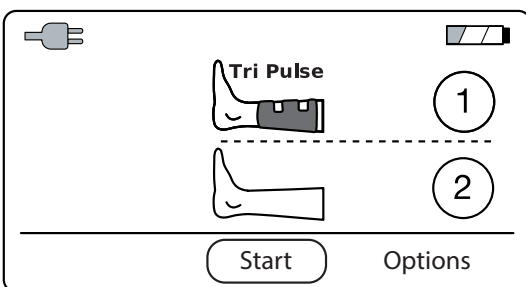
Uniform DVT Calf (or Calf & Thigh)
Garment Connected to Tubeset 1



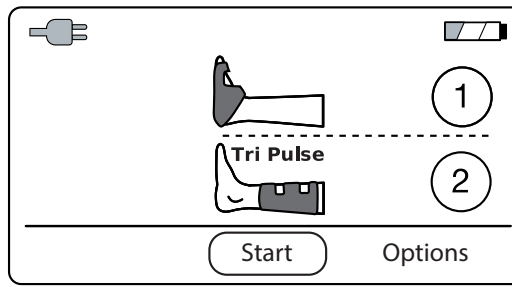
Two Uniform DVT Calf (or Calf &
Thigh) Garments Connected



Foot and Uniform DVT Calf (or
Calf & Thigh) Garments Connected



Tri Pulse Calf (or Calf & Thigh)
Garment Connected to Tubeset 1



Foot and Tri Pulse Calf (or Calf & Thigh)
Garments Connected

Starting Therapy Make sure the garment(s) are fitted correctly to the patient and the pump.

Make sure any pump options have been changed if necessary.

 *If the pump is to be positioned under a bed, make sure it is placed horizontally (with the bed-hooks underneath) to prevent damage to the pump.*

While the pump is in Standby, the LEDs on the front case remain extinguished.

Press the button below “Start” to start the therapy. The LEDs on the front case change to static green.

It is recommended that the following checks are carried out at the start of, and throughout, the therapy:

- Check the LCD screen icons to confirm that the correct type of garment(s) have been connected.
- During garment inflation, check the LCD screen to confirm that there are no fault messages displayed and that the correct pressure is being supplied. The supplied inflation pressures for the different garments are:

- Foot garment: 130 mmHg.
- Uniform DVT calf and calf & thigh garments: 40 mmHg.
- Tri Pulse calf and calf & thigh garments: 45 mmHg.

 *Initial inflation cycles (up to 10) may not show the correct inflation pressure. This is to be expected.*

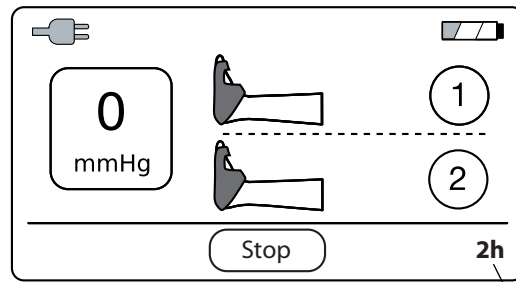
- Check that there are no kinks in the pump tubesets.
- Check that the pump tubesets and connectors do not cause the patient any discomfort.
- Regularly check that the garments remain correctly fitted to the patient.

The pump will inflate and deflate each garment in turn, as follows, starting with garment 1:

 *The following example shows two foot garments fitted to the pump.*

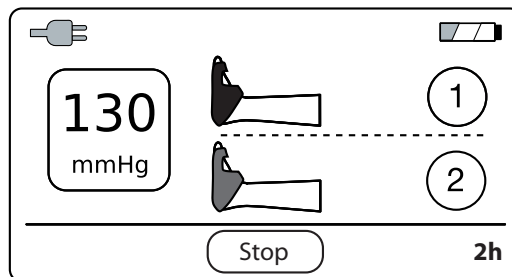
1. Both garments are initially deflated. The garment pressure is displayed on the left side of the screen. If the Patient Hours Meter is selected in the “Options” menu (refer to “Changing Options” on

page 16), the total elapsed time (in hours) is shown in the bottom right of the screen:

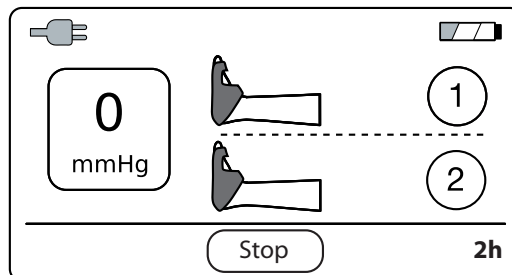


Patient Hours Meter

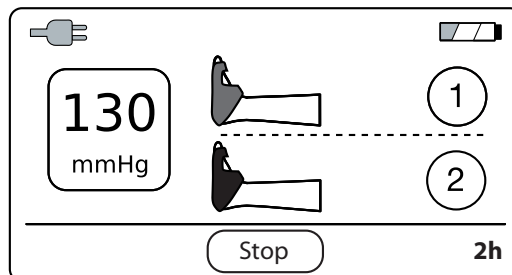
2. Foot garment 1 is inflated to 130 mmHg, with a ramp up and hold time of 3 seconds. The foot garment indicator is black while it is inflated:



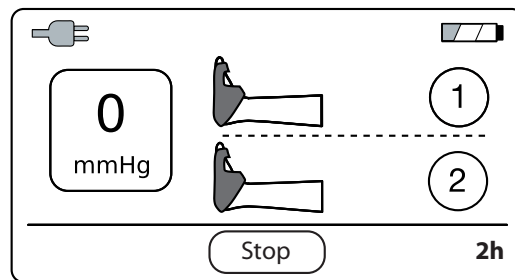
3. The foot garment is deflated to zero. Both garment indicators are grey:



4. Foot garment 2 is then inflated to 130 mmHg, with a ramp up and hold time of 3 seconds. The foot garment indicator is black while it is inflated:



5. The foot garment is deflated to zero. Both garment indicators are grey:



6. This cycle of alternate garment inflations repeats from step 2 (above) until the therapy is stopped.

If calf (or calf & thigh) garments are attached to the pump, then each of these garments is inflated to 40 mmHg (uniform DVT) or 45 mmHg (Tri Pulse), with a ramp up and hold time of 12 seconds.

If a foot garment, uniform DVT calf (or calf & thigh) or Tri Pulse calf (or calf & thigh) garment are attached to the pump, then since the inflate and hold times for a foot garment are shorter than for a calf (or calf & thigh) garment, there is a modified inflation sequence: the foot garment is always inflated twice in succession and then the uniform DVT calf (or calf & thigh) or Tri Pulse calf (or calf & thigh) garment is inflated, as follows.

 *The first garment to be inflated is always garment 1.*

1. Inflate the foot garment to 130 mmHg.
2. Deflate the foot garment.
3. Repeat the inflation of the foot garment to 130 mmHg.
4. Deflate the foot garment.
5. Inflate the uniform DVT calf (or calf & thigh) garment to 40 mmHg or the Tri Pulse calf (or calf & thigh) garment to 45 mmHg.
6. Deflate the uniform DVT calf (or calf & thigh) garment or Tri Pulse calf (or calf & thigh) garment.
7. This cycle of garment inflations repeats from step 1 (above) until the therapy is stopped.

Stopping Therapy

To stop the therapy and put the pump into Standby, press and hold the Start/Stop button for approximately 2 seconds until the Standby screen is displayed (refer to “Standby Screens” on page 11) and then release it.

The LED indicator by the On/Off button changes to amber and the LEDs on the front case are extinguished.

If the pump stays in Standby, then:

1. After 5 minutes the LCD display backlight is dimmed.
2. After a further 15 minutes (20 minutes total) the pump automatically switches off.

 *The LED indicator will remain amber if the pump is connected to the mains power and extinguished if the mains power is disconnected.*

Switching Off the Pump

1. Make sure the therapy is stopped and the pump is in Standby (refer to “Stopping Therapy” on page 15).
2. Press and hold the On/Off button for approximately 2 seconds until the LCD screen goes blank and then release it.

 *The LED indicator will remain amber if the pump is connected to the mains power and extinguished if the mains power is disconnected.*

Alarms

On detection of a fault condition, the pump provides a visual-only warning followed by an audible and visual alarm if the fault is not cleared.

1. The visual-only warning is a fault message on the LCD screen. The LED indications remain unchanged and there is no audible alarm.
2. If the fault is not cleared then the warning is replaced by an audible and visual alarm, which consists of:
 - A fault message on the LCD screen.
 - The LED indicators on the front of the pump change to red and start flashing.
 - An audible alarm will sound which increases in pitch and intensity if the alarm is ignored.

The warning and alarm can be cleared by either:

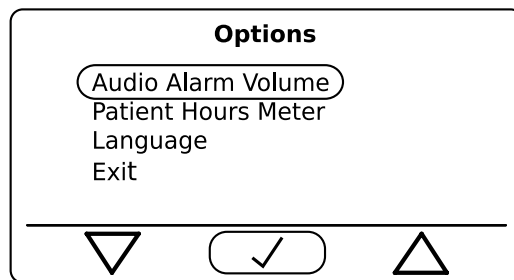
- Checking and rectifying the fault on the system, or
- Pressing the button below “Stop” to put the pump into Standby.

Refer to Section 7, Page 23 “Troubleshooting” for the alarms, their possible causes and their remedies.

Changing Options

To change the pump operating options, the pump must be in Standby. If the pump is in Run mode, press and hold the button below “Stop” for 2 seconds to put the pump into Standby.

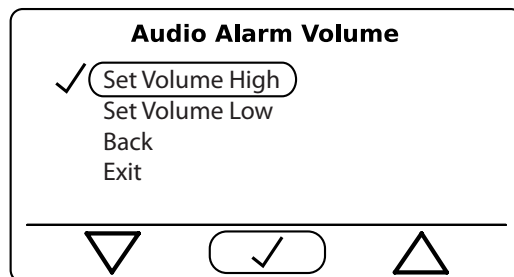
On the Standby screen, press the button below “Options” and the “Options” menu is displayed:



- The “border” around an item indicates the currently selected item.
- To select a new menu item, press the buttons below the “up” and “down” arrows.
- To confirm the new menu item, press the button below the “tick”.
- To exit and return to the Standby screen, select and confirm “Exit” on the menu.

1. To change the Audio Alarm Volume setting:

- On the “Options” menu, select and confirm “Audio Alarm Volume” and the “Audio Alarm Volume” screen is displayed:



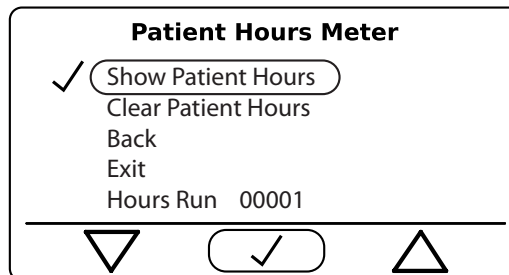
- The “tick” on the left side of the screen shows that the alarm is currently set to High Volume.
 - Use the “up” and “down” buttons to select the new volume setting. Press the “tick” button to confirm the new volume. The “tick” now shows the new setting.
 - To exit and return to the Standby screen, select and confirm “Exit”.
 - To change another option, select and confirm “Back” and the “Options” menu is displayed.
2. The Patient Hours Meter settings.

When selected, the Patient Hours Meter shows the total therapy time at the bottom right of the LCD screen during therapy.

 *This is the elapsed time since the Patient Hours Meter was last cleared using these commands.*

To change the settings:

- On the “Options” menu, select and confirm “Patient Hours Meter” and the “Patient Hours Meter” screen is displayed:



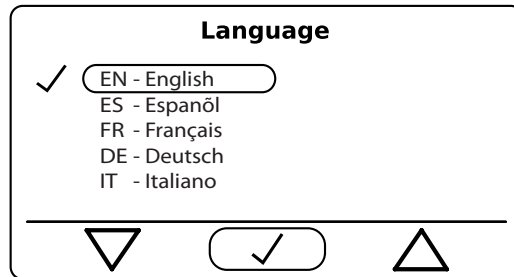
- A “tick” to the left of “Show Patient Hours” indicates that the total therapy time is shown in the bottom right of the LCD screen during therapy.
- To change this setting, use the “up” and “down” buttons to make sure the “Show Patient Hours” option is selected, and then press the “tick” button to toggle the option on or off.
- The text “Hours Run 00001” indicates the current value of the Patient Hours Meter.
- To clear the elapsed time showing in the Patient Hours Meter (for example, when therapy is started on a new patient), use the “up” and “down” buttons to select the “Clear Patient Hours” option.
- Press the “tick” button **TWICE** to clear the “Hours Run” to “00000”. The Patient Hours Meter on the LCD screen will show “0h” during therapy, if selected.

 *You must press the “tick” button twice.*

- To exit and return to the Standby screen, select and confirm “Exit”.
- To change another option, select and confirm “Back” and the “Options” menu is displayed.

3. To select a new Language:

- On the “Options” menu, select and confirm “Language” and the “Language” screen is displayed:



- The “tick” on the left side of the screen shows that the language is currently set to “English”.
- Use the “up” and “down” buttons to select the new language, e.g. “FR - Français”:



The list of languages depends on the territory, but is typically:

EN - English

ES - Español

FR - Français

DE - Deutsch

IT - Italiano

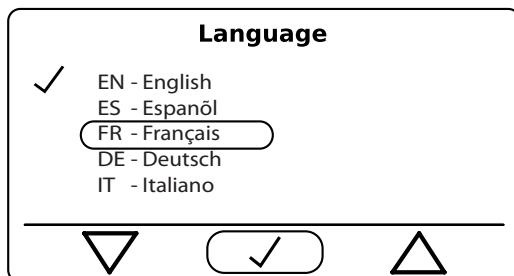
NL - Nederlands

PT - Português

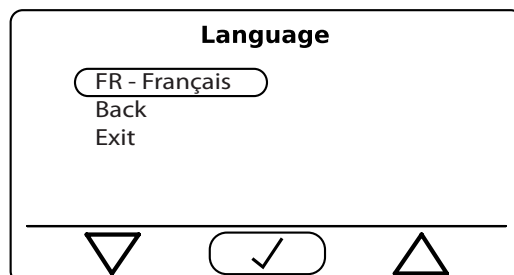
SV - Svenska

NO - Norsk

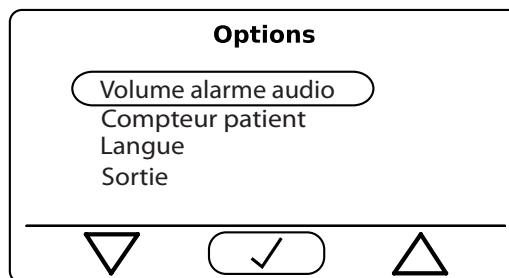
DA - Dansk



- Press the “tick” button to confirm that “French” has been selected.
- A second confirmation screen is displayed with just the new language (French) displayed:



- Press the “tick” button to confirm the change of language to French.
- The screen now displays the “Options” menu in the new language (French):



To exit and return to the Standby screen, select and confirm “Sortie”.

Settings Adjustment

The pump is configured to give the recommended therapy for each garment type and does not require any direct setting by the clinician or nurse.

If the physician requires different therapy settings for uniform DVT calf and calf & thigh garments, then limited changes can be made to the pump pressure by accessing a Service screen on the pump. Contact your local ArjoHuntleigh sales office for details.

- ☞ *The pump pressures for Foot garments and Tri Pulse calf and calf & thigh garments are fixed and cannot be changed.*
- ☞ *The pressure range and factory default pressure for the uniform DVT calf and calf & thigh garments are detailed in the “Technical Specification” on page 30.*

5. Decontamination

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility or the country of use. If you are uncertain, you should seek advice from your local Infection Control Specialist.

The system should be routinely decontaminated between patients and at regular intervals while in use; as is good practice for all reusable medical devices.

WARNING

Remove the electrical supply to the pump by disconnecting the mains power cable from the mains power supply before cleaning.
Protective clothing should always be worn when carrying out decontamination procedures.

Caution

Do not use Phenol-based solutions or abrasive compounds or pads during the decontamination process as these will damage the surface coating. Avoid immersing electrical parts in water during the cleaning process. Do not spray cleaning solutions directly onto the pump. Do not immerse the tubeset in water.

To clean Clean all exposed surfaces and remove any organic debris by wiping with a cloth moistened with a simple (neutral) detergent and water.

Do not allow water or cleaning solutions to collect on the surface of the pump.

Chemical Disinfection We recommend a chlorine-releasing agent, such as sodium hypochlorite, at a strength of 1,000ppm available chlorine (this may vary from 250ppm to 10,000ppm depending on local policy and contamination status).

Wipe all cleaned surfaces with the solution, then wipe using a cloth moistened with water and dry thoroughly.

Alcohol based disinfectants (strength 70%) may be used as an alternative.

Ensure the product is dry before storage.

If an alternative disinfectant is selected from the wide variety available, we recommend that suitability for use is confirmed with the chemical supplier prior to use.

Caution

Garments are single patient use and hence cannot be cleaned or reused.

6. Routine Maintenance

Flowtron ACS800 + Tri Pulse System

Maintenance The equipment has been designed to be maintenance-free between service periods.

Servicing ArjoHuntleigh will make available on request service manuals, component parts lists and other information necessary for ArjoHuntleigh trained personnel to repair the system.

Service Period ArjoHuntleigh recommend that the pump is serviced every 12 months by an ArjoHuntleigh authorised service agent.

Pump

General Care, Maintenance and Inspection Check all electrical connections and power cable for signs of excessive wear.

Check the tubeset and connectors for any damage.

In the event of the pump being subjected to abnormal treatment, e.g. immersed in water or dropped, the unit must be returned to an authorised service centre.

Serial Labels The serial number for the pump is on the label on the back of the pump case.

Quote this serial number when requesting service.

7. Troubleshooting

On detection of a fault condition, the pump provides a visual-only warning followed by an audible and visual alarm if the fault is not cleared.

Warning Conditions

The visual-only warning is a fault message on the LCD screen. The LED indications remain unchanged and there is no audible alarm (except Battery Low warning).

The warning can be cleared by either:

- Checking and rectifying the fault on the system, or
- Pressing the button below “Stop” to put the pump into Standby.

Alarm Conditions

If the fault is not cleared then the warning is replaced by an audible and visual alarm, which consists of:

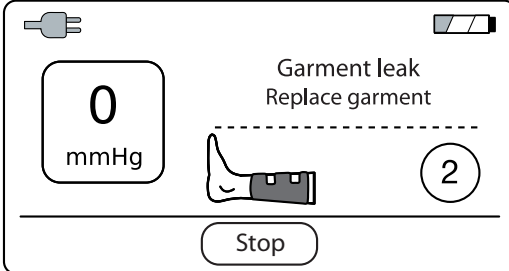
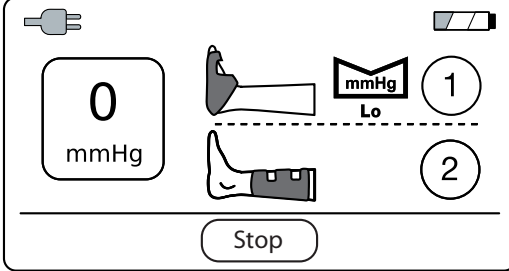
- A fault message on the LCD screen.
- The LED indicators on the front of the pump change to red and start flashing.
- An audible alarm will sound which increases in pitch if the alarm is ignored.

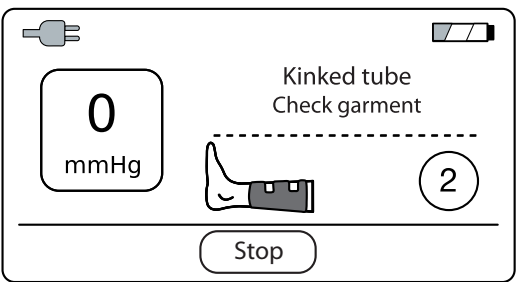
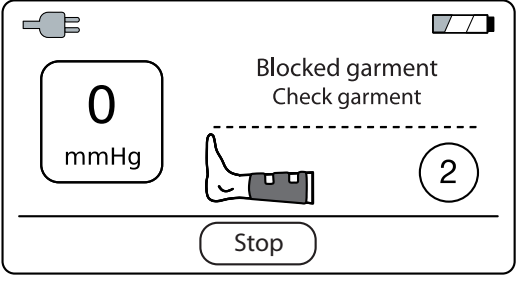
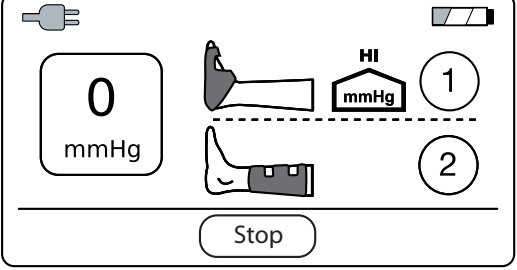
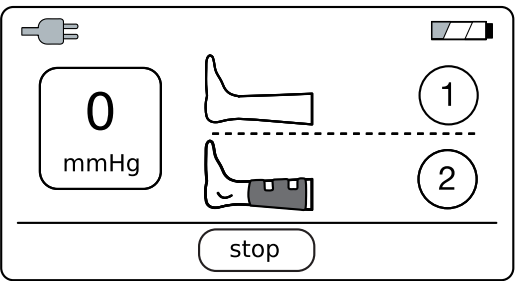
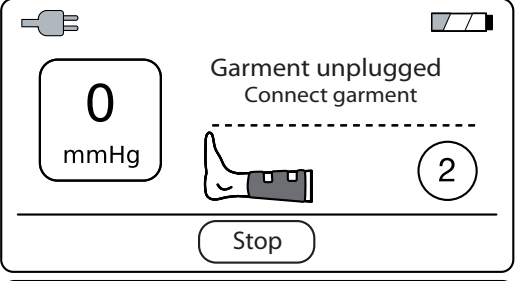
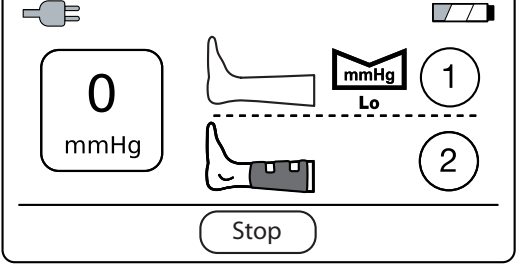
The alarm can be cleared by either:

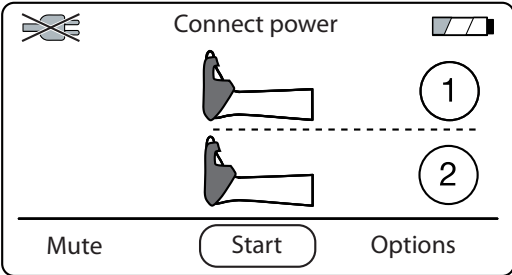
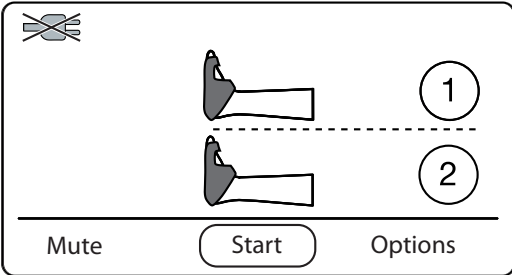
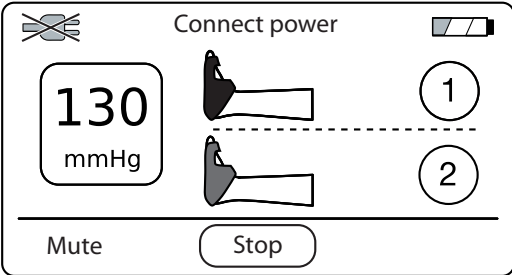
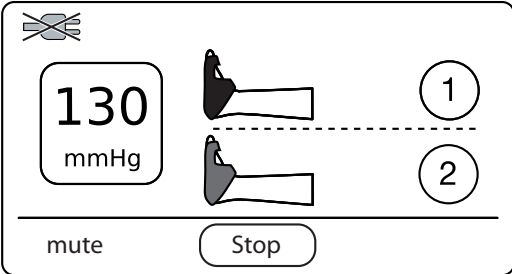
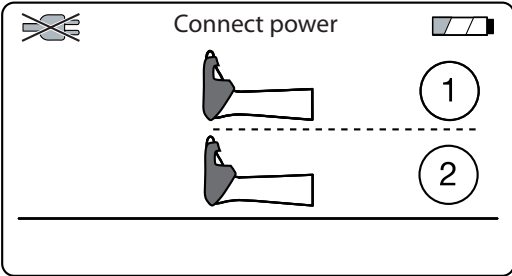
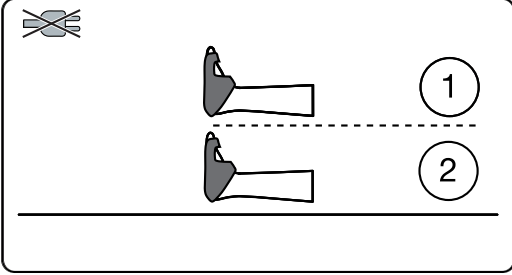
- Checking and rectifying the fault on the system, or
- Pressing the button below “Stop” to put the pump into Standby.

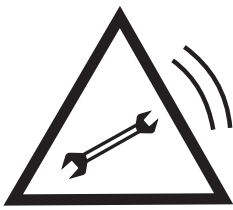
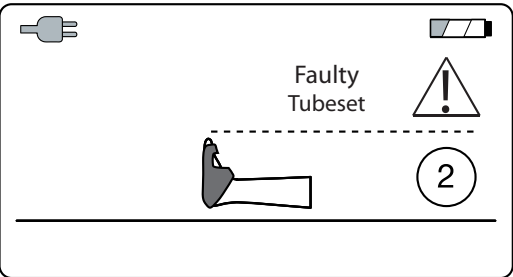
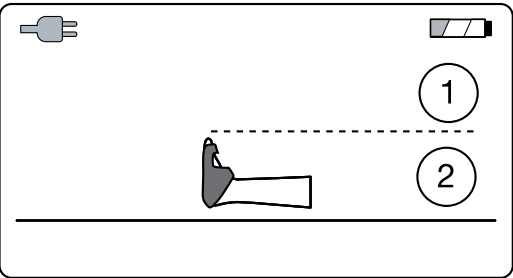
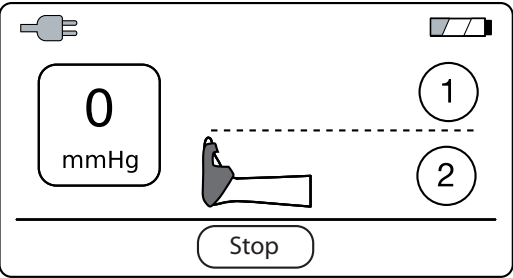
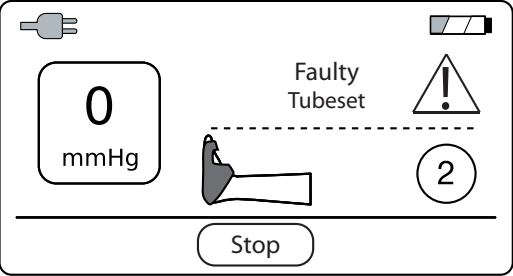
 For simplicity, the following screens (except Battery Low, Hardware Fail and Pump Too Hot) show a fault detected on garment 1; similar fault messages are displayed if the fault is detected on garment 2 (or both garments).

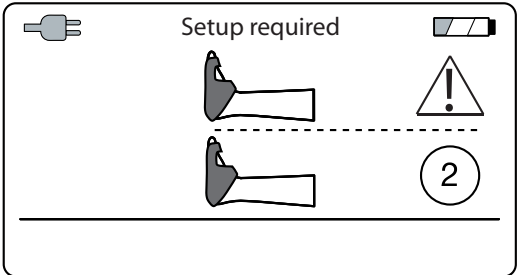
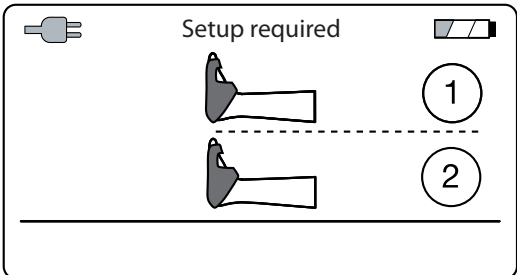
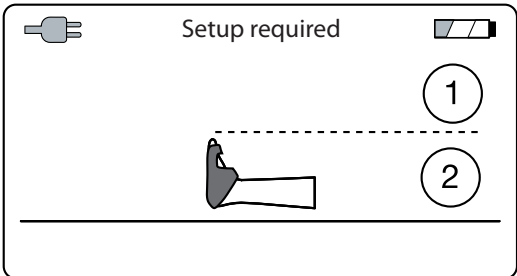
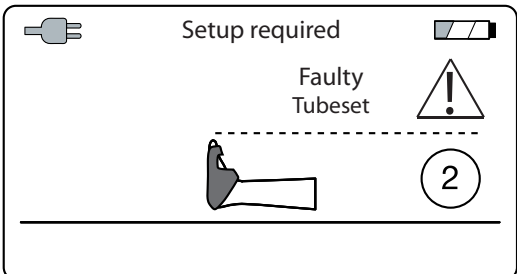
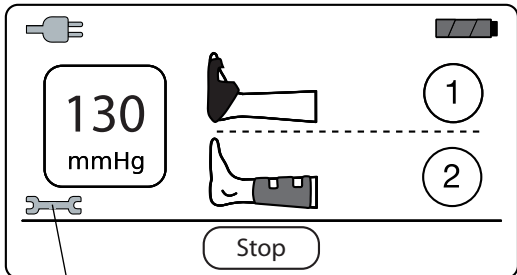
 If the trouble shooting procedures do not return the system to normal performance, stop using the system immediately and call the service engineer.

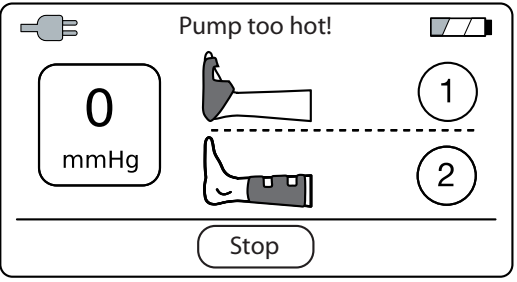
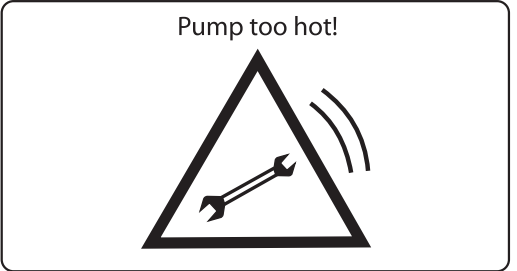
Condition	Description and Corrective Action
Low Pressure  	The warning is activated after 4 inflation cycles and shows a leak in garment 1 or its tube. Screen A alternates with the “standard” Run screen. The warning changes to an alarm after 10 inflation cycles and shows a leak in garment 1 or its tube. Screen A alternates with screen B. Examine the garment and tubeset for leaks. The warning or alarm will be cleared if the leak is repaired.

Condition	Description and Corrective Action
Blocked Garment/Kinked Tube  Kinked tube Check garment 0 mmHg Stop 2 A  Blocked garment Check garment 0 mmHg Stop 2 B  0 mmHg HI mmHg Stop 1 2 C	The warning is activated after 3 inflation cycles and shows a blocked garment 1 or kinked tube. Screens A and B alternate with the “standard” Run screen. The warning changes to an alarm after 10 inflation cycles and shows a blocked garment 1 or kinked tube. Screen C alternates with screens A and B. Examine the garment and tubeset for kinks or blockages. The warning or alarm will be cleared if the kink or blockage is repaired.
Garment Removed  Garment unplugged Connect garment 0 mmHg stop 1 2 A  Garment unplugged Connect garment 0 mmHg Stop 2 B  0 mmHg Lo mmHg Stop 1 2 C	This warning is activated after 1 inflation cycle if the pump detects that a garment has been removed while the pump is in the Run state; it shows that garment 1 has been removed. Screen A alternates with screen B. The warning changes to an alarm after 10 inflation cycles if the pump continues to detect that a garment has been removed while the pump is in the Run state; it shows that garment 1 has been removed. Screen B now alternates with screen C. Reconnect or replace the garment. The warning or alarm will be cleared if the garment is reconnected or replaced.

Condition	Description and Corrective Action
Battery Low  A  B  C  D  E  F	These Battery Low warning and alarm will only be activated when the pump is operating from just the battery (the mains power is disconnected). <i>When any of these Battery Low warning or alarm screens are activated, connect the pump to the mains power supply to recharge the battery and continue therapy.</i> If the pump is in Standby: - The warning will be activated when the remaining charge in the battery is less than 15%. Screen A alternates with screen B. Therapy can not be started. There is an audible tone when the Start button is pressed. Pressing Mute will silence the audible tone. Connect the mains power supply to the pump to clear the warning and start therapy. If the pump is in the Run state: - The warning will be activated when the remaining charge in the battery is less than 15%. There is an audible tone and screen C alternates with screen D. Therapy can continue. Pressing Mute will silence the audible tone. Connect the mains power supply to the pump to clear the warning and continue therapy. - When the remaining charge is less than 10%, the full alarm is activated. Screen E alternates with screen F. Therapy is suspended and the alarm tone can not be muted. Connect the mains power supply to the pump to clear the alarm and restart therapy.

Condition	Description and Corrective Action
Hardware Fail 	This alarm is activated if the pump detects an internal fault. The “spanner” symbol is permanently displayed. Therapy is suspended. Switch off the pump. Call the service engineer.
Faulty Tubeset  Faulty Tubeset 2 A  1 2 B  0 mmHg 1 2 Stop C  0 mmHg Faulty Tubeset 1 2 Stop D	The Faulty Tubeset warning and alarm are activated if the pump detects a fault in the tubeset. For both conditions: • Switch off the pump. • Call the service engineer. If the pump is in Standby when the faulty tubeset is detected: • A warning is activated. Screen A alternates with screen B, and shows a faulty tubeset 1. Therapy can not be started. If the pump is in the Run state when the faulty tubeset is detected: • An alarm is activated. Screen C alternates with screen D, and shows a faulty tubeset 1. Therapy can continue. • When the operator next stops the pump and puts it into Standby, the alarm reverts back to the warning in which screen A alternates with screen B, and shows a faulty tubeset 1. Therapy can not be restarted.

Condition	Description and Corrective Action
Setup Required  (A)  (B)  (C)  (D)	The Setup Required warning and alarm are activated if the pump detects a fault in the tubeset. For both conditions: • Switch off the pump. • Call the service engineer. If the pump is in Standby when the faulty tubeset is detected: • A warning is activated. Screen A alternates with screen B, and shows a faulty tubeset 1. Therapy can not be started. If the pump is in the Run state when the faulty tubeset is detected: • An alarm is activated. Screen C alternates with screen D, and shows a faulty tubeset 1. Therapy can continue. • When the operator next stops the pump and puts it into Standby, the alarm reverts back to the warning in which screen A alternates with screen B, and shows a faulty tubeset 1. Therapy can not be restarted.
Service Required  Service "Spanner" icon	The "spanner" icon appears at the lower left side of the screen to indicate that the pump requires service attention. This will normally occur after the preset service interval has expired. Therapy can continue until service is available. Call the service engineer.

Condition	Description and Corrective Action
Pump Too Hot  	This alarm is activated when the temperature inside the pump exceeds 55°C. “Pump too hot!” is displayed at the top of the “standard” Run screen (screen A) and an audible alarm sounds. Therapy can continue. Make sure the pump is connected to mains power if this alarm is activated, and check that the ventilation holes on the pump rear case are not covered or blocked. When the temperature inside the pump exceeds 60°C, the full alarm is activated. Screen B is permanently displayed and an audible alarm sounds. Therapy is suspended. Switch off the pump and allow pump to cool. Then switch back on and continue therapy. If either alarm continues, switch off the pump and call the service engineer.

8. Accessories

The *Flowtron* ACS800 + Tri Pulse pump should only be used with the following garments:

CALF GARMENTS			
Order Code	Type	Calf Circumference	Therapy
DVT10	DVT10 Standard Calf Garment	Up to 43 cm (17")	Uniform
DVT10S	DVT10S Standard Calf Garment (Sterile)	Up to 43 cm (17")	Uniform
L501-M	L501-M Standard Calf Garment	Up to 43 cm (17")	Uniform
DVT20	DVT20 Large Calf Garment	Up to 58 cm (23")	Uniform
DVT60	DVT60 Extra Large Calf Garment	Up to 71 cm (28")	Uniform
DVT60L	DVT60L Bariatric Calf Garment	Up to 81 cm (32")	Uniform
TRP10	TRP10 Regular Calf Garment	Up to 43 cm (17")	Sequential
TRP20	TRP20 Large Calf Garment	Up to 58 cm (23")	Sequential
TRP60L	TRP60L Bariatric Calf Garment	Up to 81cm (32")	Sequential

CALF & THIGH GARMENTS			
Order Code	Type	Thigh Circumference	Therapy
DVT30	DVT30 Standard Thigh Garment	Up to 71cm (28")	Uniform
DVT30S	DVT30S Standard Thigh Garment (Sterile)	Up to 71cm (28")	Uniform
L503-M	L503-M Standard Thigh Garment	Up to 71cm (28")	Uniform
DVT40	DVT40 Large Thigh Garment	Up to 89cm (35")	Uniform
TRP30	TRP30 Regular Thigh Garment	Up to 71cm (28")	Sequential
TRP40	TRP40 Large Thigh Garment	Up to 89cm (35")	Sequential

FOOT GARMENTS			
Order Code	Type	Shoe Size	Therapy
FG100	Foot Garment - Regular	UK Men/Women up to size 7 US Women up to size 9 US Men up to size 7 EURO up to size 40	Uniform
FG100S	Foot Garment - Regular (Sterile)	UK Men/Women up to size 7 US Women up to size 9 US Men up to size 7 EURO up to size 40	Uniform
FG200	Foot Garment - Large	UK Men/Women size 7½ or above US Women size 9½ or above US Men size 7½ or above EURO size 41 or above	Uniform
FG200S	Foot Garment - Large (Sterile)	UK Men/Women size 7½ or above US Women size 9½ or above US Men size 7½ or above EURO size 41 or above	Uniform

Guidance and manufacturer's declaration - electromagnetic emissions

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR - 11	Group 1	The pump uses RF energy only for its internal function. therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR - 11	Class B	The pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the pump

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	2.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientating or relocating the pump.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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